IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD. and VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE S.A.S.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS USA, INC.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. ("VFMCRP Switzerland") and Vifor Fresenius Medical Care Renal Pharma France S.A.S. ("VFMCRP France") (collectively, "Plaintiffs" or "Vifor Fresenius") hereby assert the following claims for patent infringement against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 11,446,252 ("the '252 patent" or "the Patent-in-Suit") under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Teva's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Plaintiffs' VELPHORO® drug product prior to the expiration of the Patent-in-Suit.

2. On August 25, 2022, the Court entered Final Judgment in *Vifor Fresenius Medical Care Renal Pharma Ltd. et al. v. Teva Pharms. USA, Inc.*, C.A. No. 18-390-MN. That Final Judgment enjoins Teva from launching its generic version of VELPHORO® until after the expiration of U.S. Patent No. 9,561,251 ("the '251 patent") together with the expiration of any

applicable pediatric exclusivity to which Plaintiffs are or become entitled. The '252 patent asserted in this litigation expires on November 26, 2034, several years after the '251 patent expires.

THE PARTIES

3. Plaintiff VFMCRP Switzerland is a corporation organized and existing under the laws of Switzerland with its principal place of business at Rechenstrasse 37, CH-9014 St. Gallen, Switzerland.

4. Plaintiff VFMCRP France is a simplified joint stock company (*société par actions simplifiée*) organized and existing under the laws of the Republic of France which has its principal place of business at Tour Franklin, 100-101 Terrasse Boieldieu, La Défense 8, F-92042 Paris La Défense, France. VFMCRP France is a wholly-owned subsidiary of VFMCRP Switzerland.

5. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

THE PATENT-IN-SUIT

6. On September 20, 2022, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 11,446,252, entitled "Pharmaceutical Composition, Comprising Phosphate Binder Particles." The inventors of the '252 patent are Laurent Chofflon and Erik Philipp. VFMCRP Switzerland is the assignee of the '252 patent. A copy of the '252 patent is attached hereto as Exhibit A.

THE VELPHORO® DRUG PRODUCT

7. VFMCRP France holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for

sucroferric oxyhydroxide chewable tablets, 500 mg (NDA No. 205109), sold under the trade name VELPHORO®. VELPHORO® is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. VFMCRP France received approval for VELPHORO® from the FDA in November 2013.

8. The claims of the Patent-in-Suit cover, *inter alia*, pharmaceutical formulations containing sucroferric oxyhydroxide.

9. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patent-in-Suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with VELPHORO®.

ACTS GIVING RISE TO THIS ACTION

10. On information and belief, Teva submitted Abbreviated New Drug Application No. 211411 (the "Teva ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Teva ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablets, 500 mg, (the "Teva Proposed ANDA Product"), a generic version of VELPHORO®. The Teva ANDA specifically seeks FDA approval to market the Teva Proposed ANDA Product prior to the expiration of the Patent-in-Suit.

11. On information and belief, following any FDA approval of the Teva ANDA, Teva will make, use, offer to sell, or sell the Teva Proposed ANDA Product throughout the United States, or import such generic products into the United States.

SUBJECT MATTER JURISDICTION

12. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. *See Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l*

Ltd., 887 F.3d 1117, 1123–25 (Fed. Cir. 2018), *cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, 140 S. Ct. 911, 205 L. Ed. 2d 454 (2020).

PERSONAL JURISDICTION AND VENUE OVER TEVA

13. This Court has personal jurisdiction over Teva because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

14. Venue is proper for Teva under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

COUNT I: INFRINGEMENT OF THE '252 PATENT BY TEVA

15. Plaintiffs repeat and reallege paragraphs 1-14 above as if fully set forth herein.

16. By filing the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Teva Proposed ANDA Product before the expiration of the '252 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

17. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '252 patent, Teva will further infringe at least claims 1, 6, and 11 of the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, Teva's Proposed ANDA Product is a pharmaceutical composition for oral administration in the form of a chewable tablet comprising about 2500 mg sucroferric oxyhydroxide, wherein disintegration time is between 5 minutes and 18 minutes as measured according to the European Pharmacopoeia 04/2011:20901, hardness is between 100 N to 200 N as measured according to the European Pharmacopoeia 01/2008:20908, weight is between 2000 mg and 3000 mg, more than 80% of the weight of the chewable tablet (by weight on a dry weight basis) is sucroferric

oxyhydroxide, the chewable tablet is prepared using sucroferric oxyhydroxide particles, at least 80% by volume of the sucroferric oxyhydroxide particles have a particle size in the range of 4 μm to 200 μm, and the d50 particle size distribution by volume of the sucroferric oxyhydroxide particles is in the range of 30 μm to 80 μm, thereby establishing infringement of at least claims 1, 6, and 11 of the '252 patent.

18. Teva has had knowledge of the '252 patent since at least the date of service of this Complaint.

19. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '252 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '252 PATENT BY TEVA

20. Plaintiffs repeat and reallege paragraphs 1-19 above as if fully set forth herein.

21. On information and belief, Teva has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '252 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Teva's planned manufacture, use, offer to sell, or sale the Teva Proposed ANDA Product within the United States, including in Delaware, or importation of the Teva Proposed ANDA Product into the United States, including in Delaware, or inducement or contribution to any such conduct during the term of the '252 patent, infringes any valid claim of the '252 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

22. Plaintiffs seek a declaratory judgment that Teva's manufacture, use, offer to sell, or sale of the Teva Proposed ANDA Product within the United States or importation of the Teva

Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1, 6, and 11 of the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed one or more claims of the '252 patent by filing the Teva ANDA;

B. A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the '252 patent, and/or induce or contribute to the infringement of one or more claims of the '252 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva Proposed ANDA Product until after the expiration of the '252 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the '252 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. Such other and further relief as the Court may deem just and proper.

Date: September 21, 2022

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

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